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August 27, 1986

#26

John J. Hagan
American Cyanamid Co.
1937 West Main Street
P. O. Box 60
Stamford, CT 06904-0060

RE: Patent Term Extension
Application for
U.S. Patent No. 4,224,946
Issued September 30, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,224,946 issued September 30, 1980, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on February 10, 1986, as follows:

$$\begin{aligned}\text{Period} &= \frac{1}{2} \text{ (Testing Phase) } + \text{Approval Phase} \\ &= \frac{1}{2} (872) + 379 \\ &= 815 \text{ days}\end{aligned}$$

Since the regulatory review period took place after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(4)(C) applies in the present situation because Patent No. 4,224,946 was issued (September 30, 1980) before the date of enactment (September 24, 1984) of 35 USC 156; the date an investigational device exemption (IDE) became effective involving Novafil (April 30, 1982) was before the date of enactment, and the product was not approved for commercial marketing or use (September 30, 1985) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,224,946 and Novafil cannot exceed two (2) years under 35 USC 156(g)(4)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent No. 4,224,946 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,224,946, a certificate of extension, under seal, for a period of two (2) years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

It is noted that the applicant for extension of the term of Patent No. 4,224,946 has filed an application for extension of the term of Patent No. 4,246,904, also to the product Novafil. Only one patent may be extended for any product. 35 USC 156(c)4. In the absence of an election by applicant, and in accordance with announced Office policy, if applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension of patent term will be issued to the patent having the earliest date of issuance, if the patent is determined to be eligible for extension of patent term and if the application for its extension is filed prior to the issuance of a certificate of extension of patent term of the later issued patent. Proposed rules published August 19, 1986 (1069 OG 25) \$1.785

C.E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Novafil
FDA Docket #85E-0550